Notice to applicant

List of the required documents from the researcher to be submitted to Bio Inn-EDA for clinical medical research in Egypt

Year
2025

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1. Cover letter clarifying the researcher's university/institution directed to the General Manager of General Administration of Clinical Trials signed, dated and stamped included the following items: Researcher and investigator name, study title (Original copy).

2. Applicant Request by the researcher" postgraduate or investigator initiated" for submission of the clinical medical research to the Egyptian Drug Authority.

3. Institutional Review Board (s) and/or Research Ethics Committee Approval with clear date of issuance (certified copy of original).

4. Administrative approval for the site which the clinical trial protocol is conducted (certified copy of original).

5. Study Clinical Medical Research Protocol & / or amendment.

6. Informed Consent Form.

7. Questionnaire form (if found).

8. Conflict of interest for all involved researchers.

9. Valid Insurance certificate that should be updated annually.

10. IMPD (Investigational Medicinal Product Dossier) as:
    - **10.1** Introduction of Active substance,
    - **10.2** General information regarding (nomenclature-structure-general properties-manufacturer-storage of drug substance)
    - **10.3** Commitment for use the same source of the used active substance or the same finished product itself)
    - **10.4** Specification of the active substance.
    - **10.5** Certificate of analysis (in case of use of raw material)
    - **10.6** Leaflet (in case of use of finished product).

11. Supportive documents.

12. Proof of payment of the relevant fees.